K073273

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

DEC 1 1 2007

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

New Device Name:

Trade/Proprietary Name:	EQUAL Dose 1.0
Common/Usual Name:	Radiation Therapy Verification Tool
Classification Name:	System,Planning,Radiation Therapy Treatment
Classification:	21Cfr892.5050 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
MDS Nordion	DCM1.0	K011246

Description:

MUV 1.0 is a quality assurance (QA) tool intended for independent verification of the dose calculations performed during treatment planning for external beam therapy, prior to the clinical treatment start. The intended user is a medical physicist or someone well familiar with the dosimetric concepts that are of importance in external beam therapy.

The software requires beam data for individual treatment plans to be imported through the DICOM RT Plan format. The parameters associated with the treatment delivery on the accelerator can not be edited within the software, although parameters related to the calculation inside the patient/phantom, such as the coordinates and depths of the calculation points, are open for editing.

The software is validated for broad megavoltage photon beams in the range from 4 up to 30 MV, delivered by standard medical linear accelerators (linacs).

The software runs on a Windows XP platform.

Intended use:

The legally marked predicate device has a wider intended use as the new device cited:

DCM1.0 (510K # K011246)→ DCM is a three-dimensional radiotherapy dose engine for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. Based on quality assured radiation therapy input data Dose Calculation Module (DCM) is used to plan radiation treatment with:

- Linear accelerators with X-ray energies from 4 to 50MV
- Cobalt-60 units

DCM will calculate dose for 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorized and dynamic wedges; customized blocking.

EQUAL Dose 1.0 → MUV 1.0 is a quality assurance (QA) tool intended for independent *verification* of the dose calculations performed during treatment planning for external beam therapy, prior to the clinical treatment start.

The intended user is a medical physicist or someone well familiar with the dosimetric concepts that are of importance in external beam therapy.

Summary of technological considerations:

The cleared predicate device, DCM1.0, 510(k)#: K011246, has a wide intended use than the new device EQUAL Dose 1.0. EQUAL Dose is merely a verification tool.

Name: Paul van den Biggelaar
Title: Director Oncentra
Nucletron B.V.
Veenendaal, The Netherlands

2007-08-30
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2007

Nucletron Corporation
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Service
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K073273
Trade/Device Name: EQUAL Dose 1.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 20, 2007
Received: November 21, 2007

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number	
Device Name	EQUAL Dose 1.0
Indications for Use	EQUAL Dose 1.0 is a quality assurance (QA) tool intended for independent verification of the dose calculations performed during treatment planning for external beam therapy, prior to the clinical treatment start. The intended user is a medical physicist or someone well familiar with the dosimetric concepts that are of importance in external beam therapy.

Prescription Use _X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073875